



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/833,675 | 04/13/2001 | Thomas Weimer | 06478.1454-00 | 2127 |
| 22852 | 7590 | 10/08/2003 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005 | | | LY, CHEYNE D | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1631 | |

DATE MAILED: 10/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/833,675

Applicant(s)

WEIMER, THOMAS

Examiner

Cheyne D Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-34 is/are pending in the application.
- 4a) Of the above claim(s) 26-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' arguments filed July 29, 2003 have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 10-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. This rejection is maintained with respect to Claims 10-25, as recited in the previous office action mailed May 27, 2003.

Response to Applicants' Arguments

5. Applicants argue that the phrase "mutually overlapping" is well known to those of skill in the art and thus is not vague and indefinite. Further, Applicants specify that the claimed invention is directed to "an oligonucleotide which is a single (not double) stranded nucleotide sequence." Further, Applicants cite the instant specification (page 3, lines 20-24), which recites sequence fragments comprising 30-50 bases not base pairs as support that the instant claims are not vague and indefinite. The above arguments have been fully considered and found to be unpersuasive as discussed below. It is well known in the art that amplification

reactions comprising of primers (oligonucleotide fragments) form primer dimers (double stranded) nucleotide sequences (Erich 1992).

6. Therefore, the phrase “mutually overlapping” in claims 10, line 5; 13-16, line 1; and 20, line 4, causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that a nucleic acid “mutually overlaps” with another (sequences having identical polynucleotide sequences or complementary of sense with anti-sense sequences).

Also, are overlapping DNA molecules single or double stranded? Applicant can resolve this issue by particularly pointing out the criteria that is used to determine that a series of DNA molecules are overlapping. Clarification of the metes and bounds of the instant claims is required. Claims 11, 12, 17-19, 21-25 are rejected due to being directly or indirectly dependent from claim 10 or 20.

Response to Applicants' Arguments

7. Applicants argue that the terms “universal” of claims 20 and 21 and “completely” are not vague and indefinite due the disclosure in the instant specification (page 5, lines 4-10).

Further, Applicants argument and pointed to support have been fully considered and found to be unpersuasive due the pointed to support does not help applicants resolve the vague and indefinite issue of the instant claims.

8. It is re-iterated that the term “universal” of claims 20, 6; and 21, line 1, causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that a specific base is “universal” (a base can be found any where in the universe or applicable to all purposes). Applicant can resolve this issue by particularly pointing out the criteria that is

used to determine that a specific base is “universal”. Clarification of the metes and bounds of the instant claims is required.

9. It is noted that the Examiner had inadvertently omitted claim from which claim 21 depends in the previous office action mailed May 27, 2003. Claim 20 has been added to the above rejection.

10. It is re-iterated that the term “completely” of claim 22 causes the claim to be vague and indefinite because it is unclear what criteria are being used to determine that a nucleic acid is “completely” hybridize with the target nucleic acid (degree to which a nucleic acid anneals to a target nucleic acid, or all of a specific sequence length of a nucleic acid anneals to a portion or all of the sequence length of a target nucleic acid). Applicant can resolve this issue by particularly pointing out the criteria that is used to determine that a specific hybridization is complete. Clarification of the metes and bounds of the instant claims is required.

CLAIM REJECTIONS - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 10-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Neri et al. (US 6,194,149 B1) taken with Chee et al. (US 5,837,832 A) in view of Tureci et al. (US 6,214,983 B1)

13. Neri et al. discloses the limitations to claims 10-18 and 20-25 as in previous action, mailed May 27, 2003.

14. However, Neri et al. does not disclose the limitations wherein the target nucleic acid is fragmented to produce overlapping fragments as in instant claim 10 step b).

15. Chee et al. discloses a method for identifying heterologous oligonucleotide sequences wherein target fragmentation is performed followed by target DNA amplified by PCR with primers (column 23, lines 45-67 to column 24, lines 1-4). The said method provides redundant confirmation of conserved HIV RT and other gene sequences, and the probes on will be tile through with overlap (column 25, lines 3-7 and Figure 1), as in instant claim 10 step b).

16. However, Neri et al. and Chee et al. do not disclose the oligonucleotide sequences as being identified in a DNA sequence library, as in claim 19.

17. Tureci et al. discloses a method comprising an electronic search of the GenBank database to identify know nucleic acid molecules and the results of the said search was used to generate primers (column 4, lines 9-27), as in claim 19.

18. Neri et al. discloses improvements via useful tools for rapidly analyzing nucleic acid structure as directed to basic and clinical research, and diagnostics. While, Chee et al. discloses a diagnostic method for analyzing nucleic acid molecules (column 1, lines 19-24) and Tureci et al. discloses a method for analyzing nucleic acid for diagnostics uses (Abstract etc.). Therefore, the improvements disclosed by Neri et al. is directly applicable to the method for analyzing nucleotide molecules for diagnostic uses as taught by Chee et al. and Tureci et al.

19. An artisan of ordinary skill in the art at the time of the instant invention would have been motivated to partake the improvements disclosed by Neri et al. to improve said method with

the disclosure of Chee et al. and Tureci et al. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to practice method of identifying oligonucleotides for performing target-dependent reactions with the step of target fragmentation and a sequence library as taught by Neri et al., Chee et al. and Tureci et al.

Response to Applicants' Arguments

20. Specific to claims 12-17, Applicants argue that Figure 18(a) does not disclose the limitation of a heterologous oligonucleotide of said SEQ ID. Applicants' argument has been fully considered and found to be unpersuasive because consistent with the scope of claims 12-17, a nucleotide sequence CCC of Figure 18(a) is identical to the oligonucleotide sequence of SEQ ID NO. 1 of this instant application.

21. Specific to claim 18, Applicants argue that the reference library of Neri et al. is different from the gene library of instant claim 18. Applicants' argument has been fully considered and found to be unpersuasive because consistent with the scope of claim 18 the reference library of Neri et al. is a gene library due to said reference comprising genetic information directed to one or more alleles of various organisms.

22. Specific to claim 19, Applicants argue that the GenBank search disclosed by Tureci et al. was not performed using a sequence search, but rather the search was performed using functional criteria. Applicants' argument has been fully considered and found to be unpersuasive because consistent with the scope the claim 19 which recites oligonucleotide sequences are identified in a DNA sequence database, the GenBank search according to Tureci et al. is performed in a DNA sequence database. Further, the sequence search is performed via BLAST search of the DBEST database (column 4, lines 18-19).

Art Unit: 1631

CONCLUSION

23. NO CLAIM IS ALLOWED.

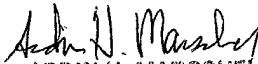
24. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

27. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
10/2/03


ARDIN H. MARSCHEL
PRIMARY EXAMINER